

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

IN RE: ZETIA (EZETIMIBE) ANTITRUST
LITIGATION

MDL No. 2:18-md-2836

THIS DOCUMENT RELATES TO:
DIRECT PURCHASER ACTIONS

**MERCK'S OBJECTIONS TO ORDER GRANTING PLAINTIFFS' MOTION TO
EXCLUDE PORTIONS OF THE PROPOSED TESTIMONY OF MARK ROBBINS**

Under 28 U.S.C. § 636(b)(1)(A) and Federal Rule of Civil Procedure 72(a), Defendants Merck & Co., Inc., Merck Sharp & Dohme Corp., Schering-Plough Corp., Schering Corp., and MSP Singapore Co. LLC (collectively “Merck”), respectfully object in part to the Order filed on August 17, 2021 (the “Order” (Dkt. 1315)) granting the Rule 702 motion filed by Plaintiffs challenging certain opinions offered by Defendants’ industry expert, Mark Robbins. Merck’s objection is limited to that portion of the Order excluding Dr. Robbins’s opinion that he disagrees with Plaintiffs and their economic experts that Defendants would have agreed to an earlier entry date in the but-for world. For all of the reasons stated herein and in the underlying briefing, Merck asks this Court to sustain these objections, set aside the affected part of the Order, and deny Plaintiffs’ Motion to Exclude Portions of the Proposed Testimony of Mark Robbins (the “Motion” (Dkt. 1056)) in part.

I. INTRODUCTION

Defendants offered testimony from Dr. Mark Robbins, an industry expert with unchallenged relevant expertise, to rebut Plaintiffs’ experts’ theory of causation in this case. Specifically, Dr. Robbins opines that based on his experience, “in a but-for world without the challenged conduct,” the parties would not “have agreed to an earlier entry date” in their settlement

agreement, much less the eighteen months to two years of additional early entry posited by Plaintiffs. Dkt. 1091-14, Robbins Rep. ¶ 74 n.52. The opinion was based on unchallenged industry expertise and the record facts of this case. Despite this, Judge Miller granted Plaintiffs' motion to exclude that opinion based on a mistaken construction of Dr. Robbins's opinion that is inconsistent both with what Dr. Robbins actually said and with how Defendants attempt to use his testimony.

The Order constitutes clear error in two distinct ways. **First**, the Order construes Dr. Robbins to improperly rely on a benchmark that is not "free of anticompetitive conduct" as the basis for his opinion about the "but-for" world. Order at 13. But that is not right. Dr. Robbins opines that *given what Glenmark knew of Merck's willingness to settle* and given unique attributes of the pharmaceutical industry, Glenmark, or a reasonable party in its position, would never have sought more than six months of early entry, *even in the absence of the alleged no-AG agreement*. Moreover, Dr. Robbins concludes that if Glenmark *made* a demand of six months' early entry, it would as a practical matter be unable to later increase its demand to more than six months, *even if* other terms of the agreement (like a no-AG agreement) were removed. The fact that Glenmark initially demanded six months of early entry, and that the jury may find it did so along with a request for a no-AG agreement, is something that Dr. Robbins takes into account in reaching his opinion about what Glenmark would have demanded in the but-for world, but Dr. Robbins does not treat that initial demand as a benchmark for the settlement in the but-for world, as the Order implies.

Second, having so construed Dr. Robbins's opinion, the Order concludes that the opinion is inadmissible because it "does not provide an economic analysis free of the challenged conduct." Order at 21. This too is error. Dr. Robbins was clear at deposition that he did not provide an economic analysis *at all*. Instead, he properly applied his undisputed *industry expertise* to the facts

of this case, explaining what parties would reasonably offer, demand, and agree to in the absence of the challenged provision when Merck had expressed a willingness to consider only a very small amount of early entry. Judge Miller has allowed Plaintiffs to offer similar industry-based expert testimony about what parties would or would not do in the but-for world from Luis Molina, who purports to draw on industry expertise to opine that, absent a no-AG agreement, “Merck, or a reasonable pharmaceutical company in Merck’s position, would have launched an AG version of Zetia to compete with the first generic competitor.” Dkt. 1314 at 2. Dr. Robbins’s opinion regarding how the unique incentives that are present in the Hatch-Waxman Act context affect the amount of early entry that a generic company would expect, propose, or agree to in the absence of the challenged conduct will assist the jury in understanding what a but-for world would actually look like as a matter of reality, not economic theory. Allowing Mr. Molina to testify while excluding Dr. Robbins’s challenged opinion is error and manifestly unfair.

The formulation of Plaintiffs’ proposed but-for world by their own paid expert economists is based on speculation layered on speculation, and Defendants have moved to exclude it in motions that remain pending. That testimony should not be admitted into evidence. But because those motions are not yet decided, and until that testimony is excluded, Defendants must retain the right to rebut speculation from economists about what a rational party might have done in a but-for world with *concrete, record-based* opinion testimony about what real industry participants would actually do. Judge Miller’s Order would prevent Defendants from offering well-reasoned opinion testimony from an unquestionably qualified industry expert on an issue squarely within the expert’s expertise, even though that opinion directly rebuts the primary theory that Plaintiffs seek to offer. That exclusion is highly prejudicial to Defendants and clearly erroneous. Accordingly, Merck respectfully requests that the Court set aside the portion of the Order

excluding Dr. Robbins's opinion in footnote 52 and deny the relevant aspect of the Motion.¹

II. LEGAL STANDARDS

Under Federal Rule of Civil Procedure 72(a), this Court must set aside a magistrate judge's ruling on a non-dispositive matter that is clearly erroneous or contrary to law. *See* Fed. R. Civ. P. 72(a) ("When a pretrial matter not dispositive of a party's claim or defense is referred to a magistrate judge to hear and decide, the magistrate judge must promptly conduct the required proceedings and, when appropriate, issue a written order stating the decision. . . . The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law."); *see also* 28 U.S.C. § 636(b)(1)(A).

"Expert testimony is admissible under Rule 702 . . . if it concerns (1) scientific, technical, or other specialized knowledge that (2) will aid the jury or other trier of fact to understand or resolve a fact at issue." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999). Experiential testimony like that offered by Dr. Robbins is admissible where the expert can explain "how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (alterations omitted) (quoting Fed. R. Evid. 702 advisory committee's note 2000).

¹ The Court also excluded the portion of Dr. Robbins's opinion that rebutted the testimony of Plaintiffs' expert Mr. Upadhye, based on its exclusion of Mr. Upadhye's testimony. Order at 10–12. Merck agrees that, if Mr. Upadhye's testimony remains excluded, Dr. Robbins's testimony is unnecessary. To the extent the Court later reconsiders the exclusion of Mr. Upadhye, however, Dr. Robbins's testimony should likewise be admitted for all of the reasons set forth in the briefing filed and arguments made before Judge Miller. Merck reserves the right to so argue if the current landscape, which does not include testimony from Mr. Upadhye, were to change.

III. ARGUMENT

A. Opinion of Dr. Robbins

Defendants offered the testimony of Dr. Mark Robbins as an industry expert to address what would have occurred in the “but-for world” if Merck and Glenmark had not entered into the challenged settlement. Dr. Robbins is unquestionably qualified; Plaintiffs did not claim otherwise. Order at 4. Indeed, the Order notes that Dr. Robbins “has worked in the pharmaceutical industry for more than thirty years [and] holds both a Ph.D. in Pharmacology from the University of Minnesota Medical School and a J.D. from St. Louis University School of Law.” *Id.* Dr. Robbins has deep experience in patent litigation in the pharmaceutical context, including under the Hatch-Waxman Act. At Upsher-Smith Laboratories, Dr. Robbins served as General Counsel and Vice President of Legal and Regulatory Affairs before becoming the Chief Scientific Officer and Executive Vice President of Legal, Scientific and Technical Operations. *Id.* at 4–5. Since leaving Upsher-Smith in 2011, Dr. Robbins has consulted pharmaceutical companies on regulatory and legal matters. *Id.* at 5.

In short, there is no dispute that Dr. Robbins has deep industry experience. And as Judge Miller acknowledged, “Plaintiffs also do not challenge the majority of Robbins’ testimony.” Order at 5. Among Dr. Robbins’s unchallenged opinions about the but-for world are the opinions that (i) even if Glenmark had won its patent litigation against Merck or had obtained an earlier entry date, Glenmark would have lacked necessary FDA approval until at least June 26, 2015; (ii) even if Glenmark had been able to launch, it would not have launched at-risk; and (iii) even if Glenmark had won its patent litigation against Merck or had obtained an earlier entry date, no other generic manufacturer could have entered the market any earlier than it actually did, with limited potential exceptions. Dkt. 1091-14, Robbins Rep. at ¶¶ 13–14.

What Plaintiffs challenged instead was Dr. Robbins’s opinion addressing Plaintiffs’

argument that, if the parties had not agreed to the challenged limited license provision (which Plaintiffs erroneously refer to and treat as a “no-AG”), they “would have agreed to an earlier entry date in a but-for world without the challenged conduct.” *Id.* ¶ 74 n.52. Dr. Robbins opined as follows:

With respect to Plaintiffs’ allegation that the parties would have agreed to an earlier entry date in a but-for world without the challenged conduct, I disagree. The testimony and documents reflect that Glenmark’s opening demand was six months of early entry, and that Glenmark understood that the six month figure would be negotiated down. *See* 10/16/19 Deposition of Vijay Soni (“Soni Depo.”) at 107:13-108:5, 228:21-229:8, 241:15-242:22; GLENMARK-ZETIA-0034970; GLENMARK-ZETIA-00281992. Based on my experience as a General Counsel in the pharmaceutical industry, once such a demand is made, it serves as a “bookend” for future negotiations and both parties understand that any ultimate settlement would be less early entry. Moreover, while Vijay Soni of Glenmark testified that Merck expressly informed him that it would not agree to a no-AG provision, he did not respond to that position by demanding an earlier entry date. *See* Soni Depo. at 109:7-21, 112:7-113:5; GLENMARK-ZETIA-00304970. To the contrary, the evidence reflects that there was no connection in the negotiations between the entry date on the one hand and any request for a no-AG provision on the other. *See* 10/15/19 Deposition of Timothy Hester (“Hester Depo.”) at 58:11-58:24, 76:7-23; 10/18/19 Deposition of Paul Matukaitis (“Matukaitis Depo.”) at 229:6-23; 11/26/19 Deposition of Lisa Jakob (“Jakob Depo.”) at 288:2-8; 10/24/19 Deposition of Lawrence Brown (“L. Brown Depo.”) at 259:10-21; Soni Depo. at 228:3-20. Under such circumstances, and based on my experience, a reasonable brand company would not agree to an entry date earlier than the first demand, and instead would expect the agreement to reflect a compromise with significantly less early entry than was first demanded.

Id.

Dr. Robbins was examined extensively at deposition on this opinion and expounded on it. Dr. Robbins explained that he was not offering “any economic assessment,” but instead had examined the negotiation history and concluded, “based upon how the parties went into the negotiation, that there would not have been an earlier entry date” *in the but-for world*. Dkt. 1137-1, Robbins Dep. 128:22–129:11. Dr. Robbins explained that in light of that negotiation history, Glenmark would not have demanded more than six months of early entry in its opening offer even if that offer had not included other proposed terms. *Id.* at 135:13–136:9. Dr. Robbins further explained that he based his opinion on the citations to the record included in footnote 52 itself, as

well as “my negotiating several settlements and license agreements, also from my role as general counsel and going to negotiations.” *Id.* at 129:20–130:11. In short, Dr. Robbins’s testimony about what would have happened “in a but-for world without the challenged conduct” was tethered to the record facts of this case and informed by his unchallenged, extensive industry experience.²

B. The Order Clearly Errs By Concluding that Dr. Robbins’s Opinion Is Not Reliable or Helpful to the Trier of Fact.

Dr. Robbins’s opinion in footnote 52 is proper expert testimony drawing on application of his industry expertise and experience to the facts of this case. Judge Miller’s exclusion of that opinion relies on a mistaken reading of Dr. Robbins as “attempt[ing] to use Glenmark’s initial offer as the benchmark” of an agreement free of anticompetitive conduct. Order at 16. Based on that erroneous understanding, Judge Miller then reasoned that “Robbins’ benchmark is not free of the allegedly anti-competitive conduct in question” because he does not “account for” and “ignores” the evidence that Glenmark’s initial offer included other terms that Plaintiffs allege are anticompetitive, including a no-AG agreement. *Id.* at 17. This finding in the Order is clearly erroneous and should not be adopted.

² In their moving papers, Plaintiffs stated the following: “This motion does not address the propriety of Dr. Robbins’ focus on what Merck and Glenmark would have done had they not violated the antitrust laws. We expect to demonstrate in motions in limine and submissions on jury instructions that the relevant issue for causation is not what Merck and Glenmark would have done absent the antitrust violation, but what reasonable companies in Merck and Glenmark’s position would have done had they not violated the antitrust laws.” Motion at 1 n.4. Because this objective/subjective distinction was not disputed in connection with the Robbins *Daubert* motion, Merck does not read Judge Miller’s opinion as adopting any view on it. This Court should similarly assume for purposes of this motion that it is proper to focus on what the parties would have done in the but-for world, as any challenge to that position was expressly disavowed by Plaintiffs in their moving papers. For the avoidance of doubt, however, Merck disagrees with the position Plaintiffs have foreshadowed and, to the extent Judge Miller’s opinion can be read as adopting that position (i.e., that what the parties would have done in the but-for world is irrelevant to causation), Merck objects to any portion of the decision that can be read in that way.

1. The Order Relies on a Misunderstanding of Dr. Robbins's Opinion.

In accepting Plaintiffs' argument that Dr. Robbins relies on a benchmark that is not "free from the effects of anticompetitive conduct," Order at 16, the Order attributes to Dr. Robbins an opinion he does not give. The decision to exclude Dr. Robbins's opinion based on this misconstruction is clear error.

Dr. Robbins's opinion addresses precisely what Judge Miller identifies as the relevant causation issue: Dr. Robbins opines that he "disagree[s]" with Plaintiffs' experts' assertion "that the parties would have agreed to an earlier entry date *in a but-for world without the challenged conduct*." Dkt. 1091-14, Robbins Rep. ¶ 74 n.52 (emphasis added). Contrary to Plaintiffs' argument and Judge Miller's understanding, Dr. Robbins does not base that opinion on any assumption or assertion that the initial demand made by Glenmark lacked the challenged conduct. Instead, he opines that *given what the record shows* about what Glenmark knew of Merck's openness to settlement—specifically, that Merck was only open to a short period of early entry—and unique attributes of the pharmaceutical industry, a reasonable party in Glenmark's position in this type of patent litigation would not request a much *longer* period of early entry than Merck had signaled willingness to consider, regardless of whether it also requested (or was offered) a no-AG. *Id.* (citing 10/16/19 Deposition of Vijay Soni ("Soni Depo.") at 107:13–108:5, 228:21–229:8, 241:15–242:22; GLENMARK-ZETIA-0034970; GLENMARK-ZETIA-00281992).

Glenmark's chief negotiator Mr. Soni, for example, conveyed to his colleagues in an email dated August 5, 2009—before Glenmark made its opening settlement demand for six months early entry—that an entry date "will be negotiated down to 3-4 months." Dkt. 1137-4, GLENMARK-ZETIA-00281992 at -93. Mr. Soni did not tie that expectation to the presence (or absence) of a no-AG agreement; indeed, his email does not mention the possibility of a no-AG agreement *at all*. Mr. Soni also testified that he "indicated to my management very clearly that the way I got a

feeling the first call, that maximum, that my sense that – this, I’m going way back to 2009 when I started discussing, that it could be maximum three to four months. That was my understanding, and that’s how it ended up practically.” Dkt. 1137–3, Soni Dep. 228:21-229:8. Dr. Robbins’s opinion is that a reasonable generic company with that knowledge of the brand’s position and a strong incentive to reach a settlement that would secure its 180-day exclusivity would not demand years of early entry, *regardless* of whether the settlement demand included a no-AG provision. And indeed, this opinion is consistent with the record here, which contains no evidence that either Merck or Glenmark based its view on the appropriate entry date on a particular assumption regarding whether the settlement would have a no-AG agreement or any other item of value. Dr. Robbins would aid the jury by explaining that Glenmark or a reasonable generic company negotiating a Hatch-Waxman settlement who is told up front that the brand is only willing to settle with a “modest” amount of early entry date would not then demand 18 months or two years of early entry simply because it cannot also get a no-AG commitment.

Moreover, given the factual record and Dr. Robbins’s experience in litigating and settling this type of case, Dr. Robbins *disagrees* with the supposition that a reasonable litigant in Glenmark’s position would have expanded the amount of early entry requested had Merck refused a request for a no-AG agreement. Dkt. 1091-14, Robbins Rep. ¶ 74 n.52. Dr. Robbins reasoned that “[u]nder such circumstances, and based on my experience, a reasonable brand company would not agree to an entry date earlier than the first demand, and instead would expect the agreement to reflect a compromise with significantly less early entry than was first demanded.” *Id.* Indeed, Glenmark’s conduct confirms this, as it responded to Merck’s rejection of a no-AG agreement by continuing to negotiate between six months early entry (Glenmark’s demand) and two months early entry (Merck’s offer), ultimately landing on 4.5 months. Dkt. 1082-11, GLENMARK-

ZETIA-0034970 at -70. Dr. Robbins’s opinion is an entirely appropriate response to Plaintiffs’ argument—and their own experts’ opinions—that when you remove a term of value during negotiation of an agreement, other terms (here the entry date) would of necessity move as well.

In other words, Dr. Robbins’s opinion is that in this context, and given the evidence of negotiations here, including the lack of any evidence that the entry date was linked to the limited license provision, it is *incorrect* to think that the insertion or removal of a no-AG or limited license provision would have any effect on the entry date. Because Judge Miller’s decision is premised on a misunderstanding of Dr. Robbins’s opinion, it is clear error.

2. Dr. Robbins’s Actual Opinion Is Reliable, Helpful, and Admissible Industry Expert Testimony.

Judge Miller’s misconstruction of Dr. Robbins’s opinion leads him to exclude that opinion for not “provid[ing] an economic analysis free of the challenged conduct.” Order at 21. But properly understood as an opinion that applies industry expertise to the facts of the case, rather than an attempted economic analysis, Dr. Robbins’s opinion is plainly reliable and helpful to the trier of fact.

Notably, Plaintiffs urged Judge Miller to make the causation question on which Dr. Robbins opines exclusively one for the hypothetical analysis of economists. At the hearing on this Motion, Plaintiffs argued that Dr. Robbins is simply “superfluous” because it is “accepted methodology in these reverse payment cases” to focus on the economists. Dkt. 1299, June 28, 2021 Hr’g Tr. 58:13-59:25. But it bears noting that reducing the evaluation of the but-for world to a battle of paid economic experts is *Plaintiffs’* proposed and preferred methodology; it is not undisputed fact. That is, Plaintiffs presume that a no-AG has such great value to a generic, and great cost to a brand company, that a reasonable generic and a reasonable brand *will agree* to a later entry date if a no-AG agreement is added. All that matters to Plaintiffs, then, is what the

economists say is the value (and cost) of the no-AG.

But Defendants and their experts are not required to adopt that presumption. An *economist* may testify as to what economically rational parties looking at certain financial numbers would do; an industry expert may testify that whatever the economist says would be rational on the numbers, the economist's theorized actions are not, in fact, what members of that industry *actually* do. In other words, Plaintiffs are free to argue that economic models are all that matters; but Defendants must also be free to argue that there is a real world that is not accurately explained by those economic models. That is precisely what Dr. Robbins has done based on his long and unquestioned industry experience.

The Order's exclusion of Dr. Robbins's opinion accepts Plaintiffs' preference for hypothetical economic analysis rather than opinions based on the record and industry facts. For example, the Order notes that it "would not be surprising" for there to be "no testimony or documentation to support Plaintiffs' hypothetical earlier entry date," since the parties were not in the but-for world. Order at 18 (citing cases). But that merely confirms why Dr. Robbins's opinion is so helpful to the jury. The jury should be free to conclude that Dr. Robbins's decades of industry expertise is *more persuasive* as an explanation of what Merck and Glenmark would have done absent the allegedly anticompetitive agreement than speculation by Plaintiffs and their paid economists that lacks any support in the record.

Notably, in helping the jury determine what settlement (if any) would have occurred in a but-for world, Dr. Robbins will be able to draw on the actual record in this case and the realities of the unique context in which the settlement occurred. That evidence reflects that when Glenmark did request a no-AG, Merck said "no," and Glenmark did not respond by demanding an earlier entry date. Even if one assumes that the final agreement did include a no-AG agreement (which

Defendants dispute and which is not a question for the Court on a *Daubert* motion), the record here still shows that there was an opportunity in the negotiations for Glenmark to demand an earlier entry date based on a refusal by Merck to commit to a no-AG, and it did not do so.

Moreover, the pharmaceutical industry and Hatch-Waxman Act litigation present a unique context in which Dr. Robbins's analysis of this record will be helpful to the jury. For example, the 180-day exclusivity period available to the first ANDA filer complicates the incentives of a first filer like Glenmark. *See* Dkt. 1091-14, Robbins Rep. ¶ 47 (explaining that a generic "will enjoy the benefits of being the first to file even if they ultimately settle . . . for minimal early entry"). As a result, a generic may have more to lose from the risk that a settlement falls apart than it does to gain from earlier entry. At the hearing on the Motion, Judge Miller equated Dr. Robbins's opinion with common experience in mediations—that "[y]ou make a demand, you don't go backwards." Dkt. 1299, June 28, 2021 Hr'g Tr. 81:19–82:10. Against that premise, he criticized Dr. Robbins for not "consider[ing] everything that he started with," including the request for a no-AG. *Id.* But Dr. Robbins's point is that *in this context*, even removing a no-AG request *will not lead* a reasonable generic company to move the entry date earlier. The negotiation of a Hatch-Waxman Act settlement is not a simple back-and-forth negotiation that can be considered devoid of context. Testimony from an industry expert such as Dr. Robbins would assist the jury in understanding that economic incentives that may apply in some transactions and industries do not necessarily apply, or apply with the same force, in the unique context of settling a Hatch-Waxman patent litigation where the generic is attempting to preserve its valuable 180-day exclusivity. Defendants have a right under the Federal Rules and due process to present this argument and evidence through Dr. Robbins.

IV. CONCLUSION

This Court should sustain Merck's Objections, set aside the affected part of the Order, and

deny the Motion as to Dr. Robbins's opinion that he disagrees with Plaintiffs' economic experts that Defendants would have agreed to an earlier entry date in the but-for world.

Dated: August 31, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will automatically email notification of such filing to all counsel of record.

DATED: August 31, 2021

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